UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,698	10/22/2001	Tim Keith	2976-4044US1	2256

27123 7590 06/23/2006

MORGAN & FINNEGAN, L.L.P.
3 WORLD FINANCIAL CENTER
NEW YORK, NY 10281-2101

EXAMINER	
SULLIVAN, DANIEL M	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 06/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,698	KEITH ET AL.	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2006 and 20 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,5,7,11,15,16,18,19,31,34,35 and 56-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2,5,11,15,16,18,19,56,57 and 59* is/are allowed.

6)☒ Claim(s) *7,31,34,35 and 58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is a reply to the Papers filed 18 January 2006 and 20 April 2006 in response to the Non-Final Office Action mailed 18 July 2005. Claims 2, 4, 5, 7, 9, 11, 15, 16, 18, 19, 31, 34, 35, 42, 46, 56-59, 112, 114, 115, 118, 120, 121, 124 and 125 were considered in the 18 July Office Action. Claims 4, 9, 42, 46, 112, 114, 115, 118, 120, 121, 124 and 125 were canceled and claims 2, 5, 11, 15, 16, 18, 19, 34, 35 and 56-59 were amended in the 18 January Paper. Claims 2, 5, 7, 11, 15, 16, 18, 19, 31, 34, 35 and 56-59 are pending and under consideration.

Response to Amendment and Arguments

Rejection of claims 4, 9, 42, 46, 112, 114, 115, 118, 120, 121, 124 and 125 is rendered moot by the cancellation thereof.

Specification

The amendment filed 20 April 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: As was stated in the 18 July Office Action with regard to the 28 January 2005 amendment, the amendment to the first line of the specification includes an incorporation by reference of the 09/881,797 Application into the instant disclosure. For applications filed prior to 21 September 2004, a priority claim under 35 U.S.C. 120 in a continuation or divisional application does not amount to an incorporation by

reference of the application(s) to which priority is claimed. As the priority claim submitted in the transmittal letter did not incorporate the disclosure of the '797 application by reference, any information incorporated by reference in the 21 September amendment that is not already present in the instant disclosure as filed constitutes new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112, first paragraph

Claim 7 **stands rejected** and claim 58 is **newly rejected** under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising the nucleic acid set forth as SEQ ID NO: 19 with the exception that the nucleotide sequence contains a single nucleotide polymorphism of guanine to adenine at position 21 of SEQ ID NO: 5969 or encoding a polypeptide comprising SEQ ID NO: 111 with the exception of an arginine to histidine substitution at amino acid 270, and vectors and isolated host cells comprising said nucleic acid, does not reasonably provide enablement for the broad scope of the nucleic acids encompassed by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

This rejection is maintained for the reasons of record and herein below in the response to Applicant's arguments. The *prima facie* case was set forth in the 28 July Office Action. It is noted that the new rejection of claim 58 was necessitated by the amendment of the claim to depend from claim 7.

Response to Amendment and Arguments

In response to the *prima facie* case of record, Applicant has amended independent claims 2 and 5 to delete the phrases containing the indefinite articles and contends that the claims are now limited to a nucleic acid comprising SEQ ID NO: 19 and comprising only one single polymorphism change from guanine to adenine at position 21 of SEQ ID NO: 5969. However, claims 7 and 58 are not limited to comprising the SEQ ID NO: 19 but instead embrace a divergent genus of polynucleotides comprising any sequence which is 90% identical to the sequence disclosed in the application. Thus, the claims still encompass a broad genus of nucleic acids that are not enabled by the teachings of the specification. Therefore, the claims stand rejected under 35 USC §112, first paragraph as lacking an enabling disclosure.

Claims 31, 34 and 35 **stand rejected** under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record and herein below in the response to Applicant's arguments. The *prima facie* case was set forth in the 28 July Office Action.

Response to Amendment and Arguments

In response to the *prima facie* case and arguments of record, Applicant again contends that the claims are not limited to therapeutic use. Applicant urges that the term "pharmaceutical" does not limit the claims to therapeutic use only and cites Dorland's Illustrated Medial

Dictionary as supporting this position because the dictionary defines "pharmaceutical" as pertaining to pharmacy or drugs and a drug as any substance, other than food, used in the prevention, diagnosis, alleviation, treatment or cure of disease. Applicant contends that one skilled in the art understands that drugs may be used in research and medicine for a myriad of uses not limited to therapeutic uses. In addition, Applicant cites passages from the specification wherein uses other than therapy are contemplated for the nucleic acid of the claims.

These arguments have been fully considered but are not deemed persuasive. The CAFC has recently found that intrinsic evidence is the primary source for determining the meaning of claim terms, since the claims themselves provide substantial guidance as to the meaning of particular terms, since claims are part of, and therefore must be read in view of, the specification, which is always highly relevant to claim construction analysis, and is the single best guide to the meaning of disputed terms, and since the prosecution history, like the specification, was created by the patentee in attempting to explain and obtain a patent, and provides evidence of how the U.S. Patent and Trademark Office and the inventor understood the patent, and thus can often inform the meaning of claim language by demonstrating how the inventor understood the invention and whether the inventor limited the scope of the invention in the course of prosecution[1].

---

[1] See *Phillips v. AWH Corp.*; 75 USPQ2d 1321 (CA FC 2005) 1328, 1329, which states, "The importance of the specification in claim construction derives from its statutory role. The close kinship between the written description and the claims is enforced by the statutory requirement that the specification describe the claimed invention in 'full, clear, concise, and exact terms.' 35 U.S.C. § 112, para. 1; see *Netword, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 [58 USPQ2d 1076] (Fed. Cir. 2001) ('The claims are directed to the invention that is described in the specification; they do not have meaning removed from the context from which they arose.'); see also *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 389 [38 USPQ2d 1461] (1996) ('[A claim] term can be defined only in a way that comports with the instrument as a whole.'). In light

In the instant case, the specification contains a section entitled "Pharmaceutical compositions" commencing at page 90. In this section, the specification teaches, "The present invention further contemplates pharmaceutical compositions useful in practicing the therapeutic methods of this invention" (p. 90, ll. 7-8). Furthermore, all of the teachings with regard to pharmaceutical compositions concern the preparation of said compositions for therapeutic administration, and the administration of said compositions to obtain therapeutic outcome. Nothing in the section that explicitly describes "pharmaceutical compositions" would lead the skilled artisan to conclude that a pharmaceutical composition as contemplated in the disclosure is other than a composition to be used therapeutically. Therefore, the intrinsic evidence clearly supports the Office position that claims to "pharmaceutical compositions" are directed to compositions intended for therapeutic use.

Finally, in the final paragraph on page 8 and first paragraph on page 9 of the 18 January Paper Applicant again contends that the specification provides enabling guidance with regard to therapeutic application of the claimed invention. In support of this contention, Applicant cites

---

of the statutory directive that the inventor provide a 'full' and 'exact' description of the claimed invention, the specification necessarily informs the proper construction of the claims. See *Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1371 [68 USPQ2d 1857] (Fed. Cir. 2003) ('A fundamental rule of claim construction is that terms in a patent document are construed with the meaning with which they are presented in the patent document. Thus claims must be construed so as to be consistent with the specification, of which they are a part.') (citations omitted). In *Renishaw*, this court summarized that point succinctly:

> Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction.

158 F.3d at 1250 (citations omitted)."

several generic teachings in the specification which are asserted to teach gene therapy methodologies and patient populations that would respond to therapy.

These arguments have been fully considered but are not deemed persuasive. As discussed in the previous Office Actions the specification provides general guidance as to how one might formulate and administer a nucleic acid to a patient and production of constructs for use in gene therapy. However, the teachings provided were routine in the art well before the instant application was filed and do not address the hurdles that the art teaches must be overcome before therapeutic application of nucleic acid pharmaceuticals is enabled.

Beyond these general teachings, the disclosure provides no specific guidance as to how one would use a pharmaceutical composition comprising the nucleic acid of the elected invention. The specification discloses that a P2X7 receptor allele comprising a SNP resulting in an arginine to histidine substitution is linked to asthma. However, it is not clear that the mutation itself is the underlying cause of the condition and, even if it were, it is unclear how administering a nucleic acid comprising the mutation would produce a therapeutic outcome. Thus, given the teachings provided in the specification, the skilled artisan would not know what patient population to treat using the claimed pharmaceutical, even if therapeutic application of nucleic acids was generally enabled.

With regard to Applicant's contention that the specification discloses patient populations that can be treated with the claimed pharmaceutical composition, the passages cited are no more than a list of conditions linked to chromosomal region 12q23-qtr and a prophetic teaching that genes found in this region can be administered to treat diseases linked to this region. This teaching is no more than the germ of an idea. As repeatedly pointed out in prosecution,

establishing any given genetic mutation as linked to a particular disease does not amount to a determination that a therapeutic effect can be achieved by administering a nucleic acid comprising that mutation. Applicant is reminded, "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." *Genentech Inc. v. Novo Nordisk* A/S CA FC) 42 USPQ2d 1001, 1005.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 USC §112, first paragraph, as lacking an enabling disclosure.

Claim Rejections - 35 USC § 112, second paragraph

Rejection of claim 34 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn in view of the amendment of the claim to depend from claim 15.

Claim Rejections - 35 USC § 102

Rejection of claims 2, 5, 7, 11, 15, 16, 18, 19 and 56-59 under 35 U.S.C. 102(e) as being anticipated by Buel *et al.* (17 October 2000) U.S. Patent No. 6,133,434 is withdrawn in view of the amendment claim amendments.

Claim Rejections - 35 USC § 103

Rejection of claims 2, 5, 11, 15, 31, 34 and 35 under 35 U.S.C. 103(a) as being unpatentable over Buel *et al.* (*supra*), as applied to claims 2, 4, 5, 9, 11 and 15 above, in view of Maniatis *et al.* (1983) Appendix A: Biochemical Techniques, *in* Molecular Cloning: a laboratory manual, Cold Spring Harbor Laboratory, pp. 461-462 is withdrawn in view of the claim amendments.

Allowable Subject Matter

Claims 2, 5, 11, 15, 16, 18, 19, 56, 57 and 59 are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

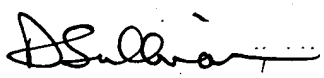
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Daniel M. Sullivan, Ph.D.
Primary Examiner
Art Unit 1636

DANIEL M. SULLIVAN
PATENT EXAMINER